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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,227	07/02/2003	Jeffrey Grossman	31132.164	1226
46333	7590	09/22/2005	EXAMINER	
HAYNES AND BOONE, LLP			POUS, NATALIE R	
901 MAIN ST			ART UNIT	
SUITE 3100			PAPER NUMBER	
DALLAS, TX 75202			3731	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/604,227

Applicant(s)

GROSSMAN, JEFFREY

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/02/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/22/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract should not begin with "the present invention," it is instead suggested that the abstract begin "An alignment system..."

The disclosure is objected to because of the following informalities: Paragraph 35 references item 22 as the proximal end of the insertion device, and paragraph 36 again references item 22 however as a proximate puncture end. The examiner will read these two references as the same item, however the disclosure should be corrected to reference each item with a single term as to avoid confusion.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A reflecting element, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Paragraph 5 of the disclosure teaches "The present alignment system comprises an insertion device, an energy source and a reflecting element." It is understood that the energy source reflects off the reflecting element onto the insertion device therefore creating an alignment trajectory. Claim 1 does not disclose the reflecting element, therefore rendering the device incapable of performing its disclosed function.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 describes an insertion trajectory device comprising an energy source and an insertion device, omitting the reflecting element described in the disclosure, therefore claiming that the trajectory system is useful without the reflecting element. See *In re Gentry*, claims must not be broader than the supporting disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission

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amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the reflecting element. It is required by the disclosure that the insertion device trajectory system include a reflecting element for the light source to reflect off of in order to create a trajectory path. Without this element, it is impossible for the device to function as disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18 and 19, are rejected under 35 U.S.C. 102(b) as being anticipated by Burgin (US 4657012).

Regarding claims 1, 4 and 8, Burgin discloses an energy source (442) for producing an energy path in a direction away from a medical insertion device indicating any trajectory correction required, and a permanent mechanism (446, 436) by which the energy source being a light source (442) is attached to the insertion device (Column 3, proximate lines 30-40)

Regarding claim 3, Burgin discloses a surface (222) for indicating the trajectory of the energy path.

Regarding claims 6 and 12, Burgin further discloses an embodiment (Figure 1) wherein the energy path comprises a directed light (132) and the attachment mechanism (32) is adapted to direct the light towards a reflecting element (52) being a reflective radiolucent material. Burgin discloses the handle portion constructed at least partially from a light-transmissive and optical waveguiding material (Column 1, proximate lines 25-30), and a portion of the handle may be polished or plated with a composition, which exhibits a mirror surface (Column 2, proximate lines 40-45).

Regarding claim 7, Burgin discloses the light source positioned so the light directed towards the reflecting element (152) is visibly identifiable on the surface (122).

Regarding claim 9, Burgin further discloses an insertion device comprising a workpiece (22) coaxial with energy source (40) producing an energy path and a visual indicator of the energy path trajectory (Column 1, proximate lines 25-32).

Regarding claim 11, Burgin discloses a visual indicator for indicating a trajectory of the energy path (Column 2, proximate lines 45-50). Burgin further discloses the invention wherein the energy path emanates from the energy source (240) in a direction away from the insertion device (261).

Regarding claims 13, 14 and 15, Burgin discloses an energy source (442) located on an insertion device (436, 446) for producing an energy path in a direction away from a medical insertion device indicating any alignment correction required, and wherein the energy path is directed towards a reflecting element (52) being a reflective

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radiolucent material. Burgin discloses the handle portion constructed at least partially from a light-transmissive and optical waveguiding material (Column 1, proximate lines 25-30), and a portion of the handle may be polished or plated with a composition, which exhibits a mirror surface (Column 2, proximate lines 40-45). Burgin discloses a surface (222) for indicating the trajectory of the energy path.

Regarding claim 16, Burgin discloses the energy source being a light source (442).

Regarding claims 18 and 19, Burgin discloses a method of aligning a medical insertion device comprising generating an energy path from an energy source located on an insertion device (Column 1, proximate lines 60-65), so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device in a direction away from the insertion device (Column 2, proximate lines 45-50).

Claims 1, and 5 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Karram (US 6428180).

Karram discloses an energy source (102) for producing an energy path in a direction away from a medical insertion device and a mechanism (112) by which the energy source can be attached to the insertion device. Karram further discloses the energy source comprising a LED (Column 4, proximate lines 10-15).

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Claims 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Paltieli (5647373).

Regarding claim 18, Paltieli discloses a method of aligning a medical insertion device comprising generating an energy path from an energy source (4) located on an insertion device (Figure 1); and reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Regarding Claim 19, Paltieli discloses the method wherein the energy path emanates away from the insertion device (Figure 3).

Regarding Claim 20, Paltieli teaches operating the insertion device through a driver (5).

Regarding Claim 21, Paltieli teaches the insertion device comprising a needle (6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karram in view of Pirtle (US 3628523). Karram discloses all aspects of claims 1 and 9 as disclosed above but does not disclose that the workpiece be a needle. Karram does however disclose that the surgical illumination device is detachably mountable in a variety of ways on any suitable surgical instrument (Column 2, proximate lines 45-55). Pirtle discloses a percutaneous needle (Column 1, proximate lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Karram with a percutaneous needle as taught by Pirtle in order to fulfill the devices capability of use on any surgical instrument.

Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitaevich (US 5598269) in view of Yanof (US 5957933). Kitaevich discloses a medical alignment system comprising an energy source (106) wherein the energy source produces an energy path (104) wherein the energy path is reflected by a reflecting element (103) and a surface (106) for indicating a location of the reflected energy path (108) so that the proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device (Column 3 lines 60-

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67), wherein the insertion device comprises a needle (100). Kitaevich does not disclose the medical insertion device wherein the energy source is located on the insertion device. Yanof teaches a medical insertion device (30) comprising needle guide (112) thereby attaching the insertion device to energy source (108). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kitaevich as with a needle guide attached to energy source to attach the insertion device to the energy source as taught by Yanof in order to increase stability of the needle and decrease the possibility of human error when the surgeon is utilizing the insertion device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6605059.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain all of the following essential elements: An insertion device trajectory system including an energy source producing an energy path away from the insertion device, an insertion device being a percutaneous needle, a surface for indicating the trajectory of the energy path, a light source adapted to direct light towards a reflecting element made of reflective radiolucent material, reflecting off the reflecting surface and onto a surface creating a visual indicator of the trajectory of the energy path. And a method by which to use the disclosed trajectory system including: generating an energy path from an energy source located on an insertion device; and reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device, wherein the energy path is in a direction away from the insertion device, operating the insertion device through a driver, and where the insertion device comprises a needle.

Regarding claim 1 of the patent Grossman discloses an insertion device located a distance from a reflecting element therefore, whereas the present application does not disclose these items in claim 1; therefore claim 1 of the application is broader than the patent. In addition, the patent does not disclose a mechanism by which patented energy source can be attached to the insertion device. Burgin (US 4657012) discloses a medical insertion device with a mechanism (436) by which the energy source (442) can be attached to the insertion device (422). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach patented energy

source to patented insertion device as taught by Burgin in order to achieve increased portability.

Regarding claim 8 of the application, Grossman discloses the energy source permanently attached to the insertion device by the attachment mechanism of claim 1. The patent does not disclose the attachment mechanism, however as stated above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach patented energy source integrally and permanently (436, 442) as taught by Burgin to patented insertion device.

Regarding claim 9 of the application, the patent claim 8 claims a "percutaneous needle alignment system", therefore indicating instrument or work piece as disclosed in claim 9 of the application as the percutaneous needle of claim 10 in the application. Coaxial, according to Merriam Webster means having coincident axes or the same axes. Claim 12 of the patent discloses the energy source emanating in a direction opposite from the device which is coaxial with the needle work piece.

All remaining claims of the application are claimed explicitly in the patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

7/19/05